



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/463,097 01/18/00 ZIMMERMANN

J 4-30096/A

001095
THOMAS HOXIE
NOVARTIS CORPORATION
PATENT AND TRADEMARK DEPT
564 MORRIS AVENUE
SUMMIT NJ 07901-1027

HM22/1024

EXAMINER

BERNHARDT, E

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.
09/463,097

Applicant(s)
ZIMMERMAN et al.

Examiner
Emily Bernhardt

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10/3/01 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search. (See NOTE below);
- (b) ☐ they raise the issue of new matter. (See NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: See attached response.

4. ☐ Applicant's reply has overcome the following rejection(s): _____
5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
of reasons set forth in the attached response.
7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
Claim(s) allowed: _____
Claim(s) objected to: _____
Claim(s) rejected: 1-8, 10, and 12-16
9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.
10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
11. ☐ Other: _____

EMILY BERNHARDT
PRIMARY EXAMINER
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The amendment filed 10/03/01 cannot be entered for the following reason: Method claim 14 as now amended would raise an additional issue, namely the scope of cancers and other diseases that are covered by the claim now limited to inhibition of BCR-abl or c-kit kinases. Additionally consideration and search for supplemental reference(s) would be needed in determining if claim 14 is still inherently anticipated and/or obvious over Zimmerman teachings alone.

Even if the amendment were entered it would not overcome the rejections of record. With regard to reason #1 under par.two the examiner continues to stress that simply reciting characterization data in whole or in part as is the case for many of the claims rejected herein without demonstrating a **material difference in scope** where none is described in the specification only serves to make the urged difference in scope unclear. For reason # 2 the examiner is aware that **alternate** processes are being claimed. What is confusing is for seemingly different crystallization techniques-i.e digestion v dissolution- the **same** solvents are recited for the **same** reactants. The 102 and 103 rejections also remain. To clarify the record claim 16 was inadvertently excluded from both of the rejections in the previous action as applicants correctly note. It (16) has been included in both rejections over Zimmerman consistent with it being held as a duplicate of claim 15 in the 112 rejection under par.two. It has also been added to the PTO cover sheet (PTOL-326) as a pending and rejected claim. This aside the rejections remain notwithstanding applicants' continued traverse. Applicants place great

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emphasis on the fact the mesylate salt was not reported to have been made by Zimmerman.

Applicants are reminded that the test for anticipation is not if a compound is actually made but if its preparation is within the knowledge of the art. See for example Ex parte A 17 USPQ 2d 1716. Zimmerman relies on routine preparation (adding methanesulfonic acid to the base in any solvent) as pointed out previously in col.19. Applicants' list of alternate processes for making one or more crystalline forms also relies on standard procedures and a whole range of solvents. It is irrelevant and as a matter of law not necessary that Zimmerman even if he made the mesylate salt of claim 11, chose not to characterize it by subjecting it to an X-ray diffraction study or any other structure determination techniques. The examiner has correctly put the burden on applicants to show that their compound cannot be made employing routine reaction conditions that would (with some trial and error) ultimately produce one or more crystalline forms claimed herein for which applicants' assignee continues to enjoy a monopoly. Claim 12 also remains rejected over Zimmerman in view of Yu for reasons of record.

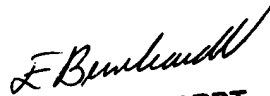
Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

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EMILY BERNHARDT
PRIMARY EXAMINER